

**RESPONSE TO OFFICE ACTION****A. Status of the Claims**

Claims 1-24 were filed and the claims amended herein. Support for the amendments is found in the claims as filed. Reconsideration of the claims is respectfully requested.

**B. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph**

The Action rejects the claims under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which Applicants regard as the invention. The individual rejections and Applicants' responses thereto are set forth below.

(1) The Action rejects claims 1-24 for including blank lines in place of ATCC Accession numbers. In response, it is noted that the claims will be amended to insert the corresponding accession numbers. The rejection is thus believed moot and removal thereof is respectfully requested.

(2) In regard to claim 3 it is indicated that it is unclear whether hybrid seed is encompassed as a plant part. Applicants note that it is and that any written description rejection of this hybrid seed is without merit as explained below and as decided by the Board of Patent Appeals.

Removal of the rejection is thus respectfully requested.

(3) The Action states that "derived" is unclear in claim 10. In response it is noted that the suggested amendment has been made and that the rejection is now moot.

(4) In claim 11 it is stated that "capable of expressing" should be deleted. Applicants respectfully traverse.

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The same rejection was made and reversed in Appeal No. 2005-0396, Application No. 10/077,589. In that case, claim 20 read as follows "20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn variety designated I082216, wherein a sample of the seed of the corn variety I082216 was deposited under ATCC Accession No. PTA-3224." The Examiner rejected the claim on the same grounds as here, namely that because the claims use the term "capable" the claims are not clear whether the plant actually expresses the traits, or when or under what conditions the traits are expressed. The Board reversed, explaining that

To address the examiner's concerns, we find it sufficient to state that if a plant has the capacity to express the claimed characteristics it meets the requirement of the claim regarding 'capable of,' notwithstanding that due to a particular phase of the life cycle the plant is not currently expressing a particular characteristic. Alternatively, if a plant is incapable of expressing the claimed characteristics at any phase of the life cycle, because it lacks, for example, the 'transcription factor' required for expression - such a plant would not meet the requirement of the claim regarding 'capable of.'

Here, we find the examiner's extremely technical criticism to be a departure from the legally correct standard of considering the claimed invention from the perspective of one possessing ordinary skill in the art. In our opinion, a person of ordinary skill in the art would understand what is claimed. *Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). We find the same to be true for the phrase 'capable of' as set forth in claims 17 and 20.

See Appeal No. 2005-0396 Board Decision at p. 12.

The issue has therefore been resolved by the Board in Applicants favor. Removal of the rejection is thus respectfully requested.

(5) In claims 16 and 21 it is stated that various terms are indefinite as "not traits" and lacking comparative basis. Applicants traverse as these are traits as much as any other. A trait is a particular phenotype and the phenotypes in this instance are both

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well known in the art and fully defined by the specification. The traits are not lacking comparative basis because the claims themselves recite these traits as being conferred by a transgene or conversion, and thus it is immediately clear that the comparative basis is a plant of the claimed variety that lacks the corresponding transgene or conversion. A more definite comparative basis could not be had. Removal of the rejection is thus respectfully requested.

(6) It is stated that the “derived” in step (a) of claim 18 is not the same as in (d). In response it is noted that the claim has been amended and that the rejection is now moot. Removal of the rejection is thus respectfully requested.

(7) Claim 19 is said to be indefinite as to the metes and bounds of “both alleles at substantially all of the loci consist essentially of the allele” and because it is unclear “how could two alleles contain one allele.” In response, it is noted that the full cited term is “wherein both alleles at substantially all of the loci consist essentially of the allele *found at the same locus in corn variety I082216*” (emphasis added). Thus it is clear that both loci are the same as the corresponding loci in variety I082216. No assertion is made that two alleles comprise one allele, rather the identity of the respective alleles is stated. There is nothing unclear or indefinite in this.

It is also stated that “consist essentially of” is unclear whether it modifies the number of alleles at the same locus or that the alleles themselves can have structural differences. In response it is noted that it is clear from the language of the claims that “consist essentially of” modifies “allele” because the full term is “consist essentially of the allele found at the same locus in corn variety I082216.” Again, there is therefore

nothing indefinite about the claim language. In view of the foregoing, removal of the rejection is respectfully requested.

**C. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement**

**1. Rejection of claims 1-24**

The Action rejects claims 1-24 under 35 U.S.C. §112, first paragraph, for lack of a seed deposit. In response, Applicant notes that a deposit of 2,500 seeds of the claimed variety will be made with the ATCC in accordance with all of the relevant rules. A declaration certifying that the deposit meets the criteria set forth in 37 C.F.R. §1.801-1.809 will be provided and the claims amended to recite the corresponding accession number. The specification will also be amended to include the accession number of the deposit and the date of deposit.

In view of the foregoing, removal of the rejection is respectfully requested.

**2. Rejection of claims 18-22**

The Action rejects claims 18-22 as not enabled. The claims are directed to methods of producing plants having the claimed inbred variety as a parent and corn plants of the claimed variety which comprise a conversion. The Action alleges, for example, that no guidance has been provided for creation of such plants and asserts non-enablement because absolute purity of backcrossed progeny may not be retained.

**a. Enablement is Demonstrated in the Specification**

The specification includes a working example describing a conversion that was made with a proprietary corn variety. This example gives the breeding history of the conversion that was made, including a description of seven backcrosses. The example describes exactly the type of process one of skill in the art could use to prepare

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conversions of the instant variety. The specification provides in great detail further guidance for creation of converted plants at pages 29-33. The techniques recited are also all well known in the art (*e.g.*, Poehlman *et al.*, 1995; Fehr, 1987; Sprague and Dudley, 1988). No basis has been provided to demonstrate why this example alone is not fully enabling as the procedures used in the example may be used to introgress any other trait within the scope of the claims.

With regard to creation of male sterile plants, this is also a technique that has been well-known for decades. This is evidenced by the numerous issued patents for creation of male sterile plants (see U.S. Patent No. 3,861,709; U.S. Patent No. 3,710,511; U.S. Patent No. 4,654,465; U.S. Patent No 5,625,132; U.S. Patent No. 4,727,219; U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242). This evidence therefore establishes the enablement of the claims and no basis to conclude otherwise has been provided as set forth below.

**b. The Reference Cited Fails to Provide a Basis for the Rejection and Affirmatively Demonstrate Enablement of the Claims**

The basis alleged by the Action for the rejection is a citation to a references said to show the difficulty of making converted plants. The reference does not support the rejection and in fact affirmatively demonstrates the enablement of the claims. For example, the Action cited Murray *et al.* (pp72-87, *Proc. 43rd Annual Corn and Sorghum Industry research*, Wilkinson *et al. eds.* 1988 American Seed Trade Assn.) for the proposition that linkage drag is common in corn breeding, that the "equivalent" of 10 backcrosses resulted in retention of 10% of the "unwanted" donor parent genome, this material would not be lost without backcrossing and selection, and that molecular marker

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assisted breeding or pedigree determination in corn is unpredictable due to a failure to identify markers specific for particular cultivars. Applicants traverse as the statements made regarding this 1988 reference both selectively misquote the teachings while ignoring directly contradictory statements and have no negative bearing on enablement.

First, the reference shows that those of skill in the art know how to produce backcrossed plants. Thus, even if it assumed that some experimentation is needed, the experimentation is not undue. Further, the authors indicate that only six backcrosses were carried out yet the authors were able to obtain plants that "approximated BC 10 in terms of inbreeding equivalence." Murray at p. 82, 2<sup>nd</sup> full ¶. There is further no basis to conclude why any additional number of generations of backcrossing would require undue experimentation. The examples in the specification mentioned above shows seven generations and any additional number of generations could be carried out using the most basic of experimentation.

Murray was also published in 1988, which Applicants submit is in no way indicative of the state of the art as of the filing date of the current application. As of March, 2002 the public USDA linkage map for maize included at least 1,006 RFLP and 804 SSR loci. In contrast, Murray states that "the current Agrigenetics maize RFLP linkage map consists of 300 independent loci." See p. 74, legend of Fig. 2; see also [http://www.ars.usda.gov/research/publications/publications.htm?SEQ\\_NO\\_115=136896](http://www.ars.usda.gov/research/publications/publications.htm?SEQ_NO_115=136896).

Despite the relatively unadvanced state of the art at the time Murray *et al.* was published, the reference in fact affirmatively establishes enablement. Murray *et al.* note, for example, that:

*Polymorphism is relatively easy to detect in maize* for several reasons. First, maize exhibits considerable genetic variability. Second

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transposition, a predominant feature of maize genome evolution, generates easily detectable polymorphism []. However, transposition is not frequent enough to cause problems in the stability and utility of most probes []. Thus, in contrast to other crops such as tomato, soybean and lettuce [], it is possible to construct maize genetic maps using only a few different restriction enzymes.

Murray at p. 76, 2<sup>nd</sup> full ¶, (citations omitted; emphasis added). Still further, just above a portion cited in the Action, the reference notes the following:

Heretofore, the process of genome recovery could only be estimated by phenotype, statistical expectation, and expensive combining ability tests. RFLP technology, on the other hand, *reveals the mosaic of parental chromosome segments* within each individual, thus *permitting the breeder to select with accuracy never before possible*.

Murray at p. 82, 1<sup>st</sup> full ¶ (emphasis added).

Finally, Murray states in another section that:

The longstanding concept of using markers flanking a desirable gene to circumvent these problems is now practical with RFLP markers. *Individuals in which recombination has occurred optimally close to the desired locus can be identified and thus linkage drag can be greatly reduced*. This technique would involve searching among a progeny with the RFLP assay to discover individuals in which the desired recombination has occurred, and then using these individual for the next backcross []. In addition, any *extraneous segments could be easily identified* or at least tested for their contribution to phenotype.

Murray at p. 84, 2<sup>nd</sup> full ¶ (citation omitted; emphasis added). This section in and of itself establishes that all of the other assertions regarding an inability to introgress a locus conversion are completely unfounded and that those of skill in the art knew how to introgress such a conversion at least as of the 1988 publication of this paper, even using the relatively lightly populated RFLP map that existed at the time. All that is required to eliminate linkage drag is to select those individuals with recombinant segments. As stated by Murray, even as of the 1988 publication date markers could readily be used to carry this out. As of the filing date of this application, extensive public marker maps

existed with at least 1,006 RFLP markers in addition to 804 SSR markers, which are both highly informative and amenable to high-throughput screening via PCR. Enablement is thus demonstrated by this reference and numerous other references also show enablement. In sum, Applicants have affirmatively demonstrated enablement of the claims and no basis for doubting this enablement has been provided. Removal of the rejection is thus respectfully requested.

**D. Rejection of Claims Under 35 U.S.C. §112, First Paragraph – Written Description**

The Action rejects claims 18 and 23-24 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to convey that Applicants were in possession of the claimed invention. For example, it is asserted that F1 hybrid progeny of the claimed variety and methods of plant breeding comprising use of the claimed variety as starting material lack written description.

**1. The Board Has Found the Rejections Made to be Without Merit**

Applicants note that the rejections made have specifically been considered and reversed by the Board of Patent Appeals on the same facts as presented in the current case. The rejections must be removed on the same basis as provided by the Board, as explained below. Specifically, in addition to Appeal No. 2005-0396, discussed above, the Board of Patent Appeals decided five other substantially similar appeals on March 31, 2005 brought by the current Real Party in Interest: Appeal Nos: 2004-1503 (Ser. No. 09/606,808), 2004-1506 (Ser. No. 09/788,334), 2004-1968 (Ser. No. 10/000,311), 2004-2317 (Ser. No. 09/771,938), and 2004-2343 (Ser. No. 09/772,520) (collectively “the corn variety appeals”). The claims and issues presented in these cases were substantively the

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same as those of the current case. Essentially identical written description rejections were raised in the prior cases relative to the current case.

In the corn variety appeals, for example, rejections were raised based on an alleged lack of written description for F1 hybrid plants. Specifically, it was alleged that the F1 hybrid plants only have as half of their genome the genome of the parent plant of interest and the remaining portion was not described, and thus written description is lacking, despite the fact that no particular second hybrid plant is required by the method. *See Board Decision at p. 17.*

The Board rejected this reasoning, noting that, as here, the claims require no particular second parent of the F1 hybrid and the Examiner had already acknowledged written description for the variety of interest. The Board also specifically disagreed with the Examiner's assertion that the fact that any hybrid plant will inherit half of its alleles from the parent variety does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants. *Id.* The Board thus held that "there can be no doubt that the specification provides an adequate written description of this corn variety." *Id.* at p. 18. As explained by the Board, the purpose of the written description requirement is to "ensure that the right of the scope to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Id.*

Here, as in the corn variety appeals, the claimed F1 hybrid plants must have the admittedly described variety of interest as one parent, and thus the claims do not overreach the scope of the inventor's contribution and are fully described. The Board rejected the notion that an Applicant must define every possible second parent plant of a

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hybrid cross and the morphological characteristics of the progeny to provide written description for claimed hybrid plants. In particular, the Board stated that it “disagree[d] with the examiner’s conclusion (id.) that ‘[t]he fact that any hybrid plant will inherit half of its alleles from [the variety of interest] then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants.’” *Id.*

Methods of plant breeding are similarly described. Essentially identical written description rejections were raised by the Examiner in Appeal No. 2005-0396 of claims drawn to a method of breeding corn plants comprising use of the variety of interest as starting material. In the appeal the Examiner argued that written description is lacking because the intermediate plants at each step of the method allegedly must be described to satisfy written description and that such plants had not been defined, regardless of the fact that the only starting material required by the claims was the variety of interest, which was admittedly fully defined. *See* p. 12-15. The Board rejected this reasoning, noting that, given the acknowledgement of written description for the variety of interest, appellants were also in possession of a method of using that plant for crossing with any other plant to produce an inbred plant as set forth in the claims. *See* Board Decision at p. 24 (“Therefore, in our opinion, there can be no doubt that appellant was in possession of a plant of the corn variety 1180580, in addition to a method of using that plant to cross with any other corn plant to produce an inbred corn plant as set forth in appellant’s claim 31”). The Board thus concluded that appellant established with reasonable clarity that they were in possession of the invention. In the context of methods of introducing transgenes, the Board noted that no evidence was provided to support the rejections or

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inadequacy of written description for the claims. The Board thus reversed the written description rejections.

The same issues have been presented here on claims of the same substantive scope. As the Board has already decided all of the rejections made here in Applicants favor in the corn variety appeals, removal of the rejection is respectfully requested.

## **2. F1 Hybrid Plants Are Fully Described**

The rejected claims are directed to F1 hybrid plants and seeds produced with corn plant I082216 as one parent. Applicants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history in the specification, corn plant I082216 is an inbred corn plant. All of the claimed hybrid plants having I082216 as a parent will therefore contain a copy of the same genome as corn plant I082216. That is, because I082216 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant I082216, save the possibility of the rare spontaneous mutation or undetected segregating locus. This entire genetic contribution of corn plant I082216 is described in the specification by way of the proffered deposit of seed of corn plant I082216 with the ATCC. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

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The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where “it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*” (emphasis added)). Here, all of the members of the claimed genus of hybrids having I082216 as one parent share the structural feature of having the genetic complement of I082216. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant I082216 is crossed with a second plant. That is, any second plant capable of reproduction may be used to make the hybrid plant. Applicants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals more than 300 utility patents issued on different corn varieties issued prior to the filing date of the current application. Any one of these corn plants, or the many hundreds or thousands of other maize plants that were known at the time the application

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was filed, could be used to produce an F1 hybrid plant having corn variety I082216 as one parent, and each of these would share the genetic complement of I082216.

Written description is reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As *any* second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, Applicants cannot be said to have not been in possession of the second parent plant. Removal of the rejection is thus respectfully requested.

### 3. Methods of Plant Breeding Are Fully Described

The Action rejects claims covering methods of plant breeding that comprise using variety I082216 as starting material as lacking written description. For example, it is asserted that plants created at any intermediate or penultimate step are not described by specific structure. However, what is required to meet the written description requirement is that an Applicant show that he or she was in possession of the *claimed invention*. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Here, a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products of the steps. The starting materials for the process must also be provided, otherwise the process could not be completed. However, the only starting materials required are corn variety I082216, which the Examiner does not allege to have not been described, and *any* second corn plant. As set forth above, corn plants were well known, and this has also therefore been fully described.

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With respect to the steps, these have been fully set forth in the claim. No essential steps have been shown to be absent. All that is required to complete the claimed method is to cross the corn variety I082216 or a product that is produced by any preceding step according to the steps given. All of the starting materials for any step within the method are either (1) corn variety I082216, (2) any second corn plant, or (3) a corn plant that is produced by following a preceding method step. The method has therefore been fully described.

It is also noted that corn breeding is well known to those of skill in the art. Without it, there would not be commercial corn varieties, which are typically sold as hybrids produced by crossing two inbred varieties. This is evidenced by the more than 300 issued patents to inbred maize varieties discussed above, given that inbred plants are not produced without multiple generations of intentional self-fertilization breeding steps. All of the steps recited in the claim are typical of the process used for the production of new corn varieties, save for the point of novelty, corn variety I082216. This is evidenced in the breeding history for the production of corn variety I082216, which is given in the specification. The specification also describes methods for producing new corn varieties in the review of related art, for example, at pages 2-4 of the application.

In conclusion, all steps of the claimed process have been recited, all starting materials have been fully described, and methods of producing new corn varieties were well known to those of skill in the art. The claims are therefore been fully described in compliance with 35 U.S.C. §112, first paragraph. Removal of the rejection is thus respectfully requested.

**E. Rejection Under 35 U.S.C. §102/103**

The Action rejects claims 23-24 under 35 U.S.C. §102/103 as being anticipated or rendered obvious by a patent said to teach some of the traits of the claimed variety. Applicants respectfully traverse as no showing that the reference actually does teach the claim limitations or for concluding that such properties are inherent has been made on the record. For example, the claims are to hybrid seed or plants having the claimed variety as one parent. This plant is admitted to be novel in the Action. As variety I082216 is an inbred plant, all of the claimed plants and seeds necessarily include half of the genome of the admittedly novel parent line. There is therefore no basis to conclude the claims read on the prior art.

Hypothetical possibilities in a rejection do not suffice to support a prior art rejection. Here, all of the claimed compositions include the genome of the variety of interest and thus are distinguishable on this bases. In contrast, the Action appears to be alleging that the cited plant *may* be the same as the claimed variety, listing several traits that appear to be the same. However, other than the recitation of a few selected traits, the Action made no attempt to show that the cited variety anticipates the subject matter of the claims. Under 35 U.S.C. § 102 it is the burden of the Office to show that *each and every* element as set forth in the claim is found in the prior art. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). This has not been done and the anticipation rejection must therefore fail.

To the extent that unexpressed inherent characteristics of the cited variety form the basis of the anticipation rejection, it is noted by Applicants that these characteristics

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must necessarily flow from the prior art. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) ("To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."). Here, it is merely stated that the cited variety shares *some* of the same characteristics and there is no showing that any other traits *are* necessarily present. The Action has thus failed to meet the burden under 35 U.S.C. §102 or §103.

Finally, Applicants note that a rejection must be supported by "substantial evidence" in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko*, 59 USPQ 2d 1693 (Fed. Cir. 2001). The current rejection is not properly supported because it is based on hypothetical possibilities. The burden has further not been shifted to Applicants because the claims define over the prior art as set forth above. No basis for the rejection has therefore been provided or exists. Removal of the rejection is thus respectfully requested.

#### **F. Conclusion**

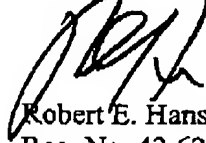
This is submitted to be a complete response to the referenced Office Action. In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested.

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The Examiner is invited to contact the undersigned at (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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